

**EXHIBIT A**  
**REDACTED IN**  
**ITS ENTIRETY**

# **EXHIBIT B**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC,  
and LEIUTIS PHARMACEUTICALS LLP,

Plaintiffs,

v.

ACCORD HEALTHCARE, INC.,

Defendant.

C.A. No. 23-377-CFC

**ANDA CASE**

**PLAINTIFFS' SUPPLEMENTAL RESPONSES AND OBJECTIONS TO  
DEFENDANT'S INTERROGATORIES (NOS. 1-13)**

Pursuant to Federal Rules of Civil Procedure 26 and 33 and the applicable Local Rules of the U.S. District Court for the District of Delaware, Plaintiffs Ingenus Pharmaceuticals, LLC and Leiutis Pharmaceuticals LLP ("Plaintiffs") hereby supplements its responses to Interrogatories (Nos. 1-13) (hereinafter "Interrogatories") served by Accord Healthcare, Inc., ("Defendant" or "Accord") as follows:

**PRELIMINARY STATEMENTS**

Plaintiffs incorporate by reference the Preliminary Statements set forth in its Responses and Objections to Defendant's First Set of Interrogatories (December 1, 2023) and Defendant's Second Set of Interrogatories (May 17, 2024).

**GENERAL OBJECTIONS**

Plaintiffs incorporate by reference the General Objections set forth in its Responses and Objections to Defendant's First Set of Interrogatories (December 1, 2023) and Defendant's Second

Set of Interrogatories (May 17, 2024).

**INTERROGATORY NO. 3:**

Separately for all experiments, studies, data, figures, tables, and examples described or referenced in the specifications of each of the Patent-in-Suit, identify: the dates, locations, title, and other identifiers (e.g., experiment number) of the experiment or study; all persons involved in the experiment or study (including former employees) and each person's role; the equipment, conditions, protocols, and/or testing methods used in the experiment or study; the batch and lot numbers of any compound(s) or formulation(s) used in the experiment or study; all documents and things (by Bates No.) referring or relating to the experiment or study, including, but not limited to, laboratory notebooks, protocols, methods, reports, correspondence, and data; and the person(s) (other than counsel) most knowledgeable about the information sought by this interrogatory.

**RESPONSE TO INTERROGATORY NO. 3 (December 1, 2023):**

In addition to the General Objections, Plaintiffs specifically object to this Interrogatory to the extent it seeks information protected by the attorney client privilege and/or the attorney work product doctrine.

Subject to the foregoing General and Specific Objections, pursuant to Rule 33(d), information responsive to this Interrogatory may be obtained from the file history of the '952 patent. See, e.g., ING00000001 - ING00000628.

Plaintiffs reserve the right to amend, supplement and/or alter this response as discovery progresses.

**SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 3 (June 13, 2024):**

Plaintiffs incorporate their general and specific objections above. Plaintiffs further specifically object to the extent the interrogatory seeks information about "the specifications of

each of the Patent-in-Suit,” as only the ‘952 patent is asserted in this suit. Subject to those objections, Plaintiffs respond further as follows.

As Plaintiffs’ indicated, information responsive to this Interrogatory may be obtained from the file history of the ‘952 Patent. ING000000001 - ING000000628. *See*, for example, ING000000231-ING000000246. Responsive information can also be found at LEI000000760-766; LEI000000777-781; LEI000000790-797; LEI000000798-801; LEI000000829-856; LEI00001110-1123; LEI00001124-1131. Kocherlakota Chandrashekar and/or Banda Nagaraju are generally knowledgeable about the examples described in the specifications of the ‘952 Patent.

**INTERROGATORY NO. 5:**

Identify and describe the roles of all persons involved in the prosecution of each of the Patent-in-Suit, including, but not limited to, the preparation, drafting, and/or submission of all responses and amendments to the PTO’s office actions and any declarations in support thereof.

**RESPONSE TO INTERROGATORY NO. 5 (December 1, 2023):**

In addition to the General Objections, Plaintiffs specifically object to this Interrogatory to the extent it seeks information protected by the attorney client privilege and/or the attorney work product doctrine.

Subject to the foregoing General and Specific Objections, pursuant to Rule 33(d), information responsive to this Interrogatory may be obtained from the file history of the ‘952 patent. *See*, e.g., ING000000001 - ING000000628.

Plaintiffs reserve the right to amend, supplement and/or alter this response as discovery progresses.

**SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 5 (June 13, 2024):**

Plaintiffs incorporate their general and specific objections above. Plaintiffs further

specifically object to the extent the interrogatory seeks information about “the specifications of each of the Patent-in-Suit,” as only the ‘952 patent is asserted in this suit. Subject to those objections, Plaintiffs respond further as follows.

Information responsive to this Interrogatory may be obtained from the file history of the ‘952 Patent, ING00000001-ING00000628. *See*, for example, ING00000491-ING00000494, ING00000285-ING00000297, and ING00000076-ING00000081. Persons involved with prosecution include at least Kocherlakota Chandrashekar and/or Banda Nagaraju (inventors and declarants), Adolph Bohnstedt, Ph.D. (patent agent) Erica Hines (patent attorney) and Chidambaram S. Iyer (patent attorney).

**INTERROGATORY NO. 6:**

For each Asserted Claim, explain in detail each objective indicia of nonobviousness, if any, that Plaintiffs contend supports the validity of the claim, including, but not limited to, any alleged commercial success and nexus to the claimed subject matter, any alleged long-felt need in the art for the claimed subject matter, any alleged failure of others to solve the problems addressed by the claimed subject matter, any alleged skepticism or disbelief by any person relating to the claimed subject matter, any alleged positive recognition in the relevant industry for the claimed subject matter, any alleged copying of the claimed subject matter, and any alleged unexpected results produced by the claimed subject matter, and identify each person with knowledge of the foregoing and all documents relating to the foregoing.

**RESPONSE TO INTERROGATORY NO. 6 (December 1, 2023):**

In addition to the General Objections, Plaintiffs further object to this interrogatory’s use of the term “knowledge” as vague, ambiguous and inherently subjective as used in the interrogatory. Plaintiffs further object to this Interrogatory to the extent Defendant seeks to impermissibly

advance the timing of Plaintiffs' disclosure of expert discovery (on an issue on which Plaintiffs do not bear the burden of proof) and to the extent that this Interrogatory is premature in that fact and expert discovery has not been completed. Plaintiffs further object to this Interrogatory to the extent it seeks a legal conclusion.

Defendant served invalidity contentions identifying prior art references and defenses on August 24, 2023. Plaintiffs have not reviewed Defendant's contentions sufficiently to have determined what, if any, objective indicia Plaintiffs may rely upon in response. **Plaintiffs will supplement this Response at the appropriate time.**

**SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 6 (June 13, 2024):**

Plaintiffs incorporate their general and specific objections above. Subject to those objections, Plaintiffs respond further as follows.

On June 6, 2024, Defendant served Plaintiff with Defendants' Amended Invalidity and Noninfringement Contentions. Plaintiffs have not reviewed Defendant's amended contentions sufficiently to have determined what, if any, objective indicia Plaintiffs may rely upon in this case, and thus reserve the right to supplement this answer after Plaintiffs complete their analysis. Subject to the foregoing, **Plaintiffs expect to rely on at least copying and long-felt need.**

**Copying**

Defendant has admitted to copying Plaintiffs' Product.

**Long-Felt But Unmet Need**

Cyclophosphamide was first approved by FDA in 1959. Historically, cyclophosphamide powder formulations have been used in both adult and pediatric patients. Powder formulations are reconstituted to a concentration of 20 mg/ml (25 ml, 50 ml, and 100 ml to dissolve the 500 mg,

1000 mg, and 2000 mg dose vials, respectively) using sterile water for injection or normal saline with vigorous shaking. Powder formulations require reconstitution to form a solution for intravenous (IV) injection. Cyclophosphamide crystals in powder preparations may be difficult to dissolve.

Powder formulation may disadvantageously require periods of time for complete dissolution, resulting in long wait times for patients and a delay in care when the product is prepared at the time of infusion. Furthermore, reconstitution of parenteral products has shown to increase the risk of product contamination and dosage errors. In addition the reconstituted and diluted solutions can be stored only for a fixed period of time without compromising the quality of the product.

Plaintiffs' FDA approval and commercial introduction of RTU formulations of cyclophosphamide in July-August advantageously reduced preparation time, decreased drug volume per dose, and reduced waste as a multidose vial. These advantages over the powder formulations were beneficial over prior powder formulations requiring dilution.

**INTERROGATORY NO. 7:**

For each Asserted Claim, identify and describe all factual and legal bases for your disagreement with Defendant's Invalidity Contentions that the Asserted Patent Claims are invalid under 35 U.S.C. §§ 102, 103, and/or 112, including all support for such disagreement, identification of any references cited in Defendant's Invalidity Contentions you allege do not qualify as prior art and why, any claim elements you allege are not disclosed by the prior art, and why each of the disclosed references and the disclosed combinations thereof do not anticipate or render obvious the Asserted Claims.

**RESPONSE TO INTERROGATORY NO. 7 (May 17, 2024):**



In addition to its General Objections, Plaintiffs specifically object to this Interrogatory to the extent that the Interrogatory seeks Plaintiffs' responses to Defendant's invalidity defenses before discovery is substantially complete. Plaintiff specifically objects to this interrogatory as overly broad and unduly burdensome in its repeated use of the term "all factual and legal bases," "all support," etc. The benefit of such overly broad discovery is completely outweighed by the burden it imposes. *See* Fed. R. Civ. P. 26(b)(2)(c); *In re MGM Mirage Sec. Litig.*, No. 2:09-CV-1558-GMN, 2014 WL 6675732, at \*5 (D. Nev. Nov. 25, 2014); *Wynn Las Vegas v. Zoggolis*, No. 14-cv-157-MMD-VCF, 2014 WL 2772241, at \*3 (D. Nev. June 17, 2014); *Switch Commc'ns Grp. v. Ballard*, No. 2:11-CV-00285-KJD, 2011 WL 3957434, at \*8 (D. Nev. Sept. 7, 2011) (*quoting Steil v. Humana Kansas City, Inc.*, 1197 F.R.D. 445, 447 (D. Kan. 2000) "However, 'to require specifically 'each and every' fact and application of law to fact ... would too often require a laborious, time-consuming analysis, search, and description of incidental, secondary, and perhaps irrelevant and trivial details.'"). Plaintiff will not provide information on "all factual and legal bases" and "all support," before substantial discovery has been conducted.

Plaintiffs further specifically object to this Interrogatory as overly broad and unduly burdensome to the extent that it requires Plaintiff to provide a narrative. *See Wagner v. St. Paul Fire & Marine Ins. Co.*, 238 F.R.D. 418, 426 (N.D. W.Va. 2006) ("Interrogatories should not require the answering party to provide a narrative account of its case. The court will generally find them overly broad and unduly burdensome on their face to the extent they ask for every fact which supports identified allegations or defenses."); *Braziel v. Lindsay*, No. 10-0678, 2011 WL 13223902 (D.N.M. Nov. 14, 2011)("a request for a narrative account of a party's case is not proper") *Id.* at 1.

Plaintiffs further specifically object to this Interrogatory to the extent it requires Plaintiff

to respond to noncompliant and incomplete contentions. D.I. 18. The Scheduling Order requires the identity of no more than 12 prior art references for any one patent. D.I. 18 ¶ 7(a). Defendant's contentions exceed this limit by stating "Accord also reserves the right to rely upon any prior art cited in any of the patents-in-suit, their file histories, or the file histories of any related patents or patent applications." Contentions p. 3. Defendant also states

"The above identification of prior art by Accord is in addition to the prior art cited in the prosecution histories of the patents-in-suit and/or in the prosecution histories of any related patents or patent applications, all of which are herein incorporated by reference in their entirety.

To the extent they constitute prior art, Accord also reserves the right to rely upon foreign counterparts of the U.S. patents identified above; U.S. counterparts of foreign patents and foreign patent applications identified above; U.S. and foreign patents and patent applications corresponding to articles and publications identified above; and any systems, products, or prior inventions that relate to any references identified above.

*Id.* Plaintiffs cannot respond to contentions based on unidentified references, and need not respond to the assertion of more than 12 prior art references for the '952 patent.

Plaintiffs further specifically object to this Interrogatory to the extent it requires Plaintiffs to respond to incomplete contentions alleging invalidity based on obviousness under 35 U.S.C. § 103, where Defendant's contentions fail to set forth the scope and content of the prior art, the level of ordinary skill in the art or any objective factors. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). Nor do Defendant's contentions set forth any motivation to combine specific teachings of specific references in a manner Defendant alleges the asserted claims are obvious, such that Plaintiffs can understand Defendant's contention and meaningfully respond.

Plaintiffs further object to this Interrogatory as seeking matters for expert discovery prior to the time for such discovery set forth in the Scheduling Order. Plaintiffs further object to this Interrogatory to the extent that it seeks a legal conclusion. Plaintiffs further object to this

Interrogatory to the extent that it seeks discovery of information that is subject to the attorney-client privilege, work product immunity, and/or any other applicable privilege or immunity. Plaintiffs further object to this Interrogatory to the extent it is compound, asking multiple questions in an attempt to evade the limits on interrogatories imposed by Federal Rule of Civil Procedure 33(a) and the Court's Scheduling Order.

Plaintiffs further specifically object to this Interrogatory to the extent it requires Plaintiff to respond to contentions that do not clearly articulate written description and enablement challenges under Section 112. Defendant contends that Patentees failed the statutory 'possession' requirement of written description, but concede Example 2 falls squarely within the scope of Claim 1 and that Patentees were in possession of that Example. Conflating the written description and enablement requirements, Defendant's enablement challenge – as presently understood- is based on the absence of any description of antioxidant in Claim 1. Plaintiffs cannot respond to contentions under Section 112 that do not clearly set forth the basis for any validity challenge. Subject to the foregoing General and Specific Objections, and without waiving any such objections, Plaintiffs state that Asserted Patent Claims are presumed valid. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011) ("Under § 282 of the Patent Act of 1952, '[a] patent shall be presumed valid' and '[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.'" ) (quoting 35 U.S.C. § 282). To the extent Defendant's contentions identify select claim elements allegedly disclosed in the prior art references, Plaintiffs refer to the prosecution history of the '952 Patent. See, e.g., ING00000001 - ING00000604.

Plaintiffs reserve the right to supplement and/or amend their response to this interrogatory in connection with the deadline for serving expert disclosures set forth in the Court's Order (D.I.

18). Discovery is ongoing, and Plaintiffs may supplement and/or amend this response as necessary in accordance with the Federal Rules of Civil Procedure.

**SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 7 (June 13, 2024):**

Plaintiffs incorporate their general and specific objections above. Subject to those objections, Plaintiffs respond further as follows.

The Scheduling Order (D.I. 18) sets the following schedule for expert reports and close of expert discovery:

Opening Expert Reports	September 27, 2024
Rebuttal Expert Reports	October 28, 2024
Reply Expert Reports	November 13, 2024
Close of Expert Discovery	November 26, 2024

As appropriate, Plaintiffs will supplement their response to this interrogatory to specify particular portions of the prosecution history of the '952 Patent in connection with the deadline for serving expert disclosures provided in the Scheduling Order (D.I. 18).

Furthermore, on June 6, 2024, Defendant served Plaintiff with Defendants' Amended Invalidity and Noninfringement Contentions. Plaintiffs have not reviewed Defendant's amended contentions sufficiently to have determined what, if any, further response to this interrogatory is appropriate and thus reserve the right to supplement this answer after Plaintiffs complete their analysis.

**INTERROGATORY NO. 9:**

If Plaintiffs contend that the intrinsic evidence of the '952 patent discloses stability data for the formulation of Example 6 of the '952 patent, identify where in the intrinsic evidence such data is disclosed.

**RESPONSE TO INTERROGATORY NO. 9 (May 17, 2024):**

In addition to its General Objections, Plaintiffs object to this Interrogatory to the extent that the Interrogatory seeks Plaintiffs' contentions regarding Defendant's invalidity defenses and Plaintiffs' infringement positions before discovery is substantially complete. Plaintiffs have no contention responsive to this interrogatory at this time. Plaintiffs further object to this Interrogatory as seeking matters for expert discovery prior to the time for such discovery set forth in the Scheduling Order. Plaintiffs further object to this Interrogatory to the extent that it seeks discovery of information that is subject to the attorney-client privilege, work product immunity, and/or any other applicable privilege or immunity.

Plaintiffs object to this Interrogatory to the extent it seeks information that is equally accessible and burdensome for Defendant to access and assess.

Subject to the foregoing General and Specific Objections, Plaintiffs respond that, pursuant to Rule 33(d), responsive information may be obtained from the file history of the '952 patent. See, e.g., ING000000001 - ING000000604.

**SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 9 (June 13, 2024):**

Plaintiffs incorporate their general and specific objections above. Subject to those objections, Plaintiffs respond further as follows.

The Scheduling Order (D.I. 18) sets the following schedule for expert reports and close of expert discovery:

Opening Expert Reports	September 27, 2024
Rebuttal Expert Reports	October 28, 2024
Reply Expert Reports	November 13, 2024
Close of Expert Discovery	November 26, 2024

Furthermore, on June 6, 2024, Defendant served Plaintiff with Defendants' Amended Invalidity and Noninfringement Contentions. Plaintiffs have not reviewed Defendant's amended contentions sufficiently to have determined what, if any, further response to this interrogatory is appropriate and thus reserve the right to supplement this answer after Plaintiffs complete their analysis.

Intrinsic evidence of the stability of the examples of the '952 Patent can be found in the '952 patent at least at, *e.g.*, Col. 4, l. 15 – Col. 7, l. 19, and at least at, *e.g.*, ING000030-33; ING000072-73; ING000079-81; ING000085-89; ING000096-100; ING0000147-50; ING0000152-55; ING0000167-70; ING0000213, ING0000232-33, and ING0000240-41.

**INTERROGATORY NO. 10:**

If Plaintiffs contend that the formulation of Example 6 of the '952 patent falls within the scope of claim 1 of the 952 patent, explain the complete basis for this contention. If Plaintiffs do not make such a contention, state that Plaintiffs do not contend that the formulation of Example 6 of the 952 patent falls within the scope of claim 1 of the 952 patent.

**RESPONSE TO INTERROGATORY NO. 10 (May 17, 2024):**

In addition to its General Objections, Plaintiffs object to this Interrogatory to the extent that the Interrogatory seeks Plaintiffs' contentions regarding Defendant's invalidity defenses and Plaintiffs' infringement positions before discovery is substantially complete. Plaintiffs have no contention responsive to this interrogatory at this time. If Defendant sets forth an invalidity contention directed to whether "the formulation of Example 6 of the 952 patent falls within the scope of claim 1 of the 952 patent," Plaintiffs will respond as appropriate in accordance with the case schedule.

Plaintiffs further object to this Interrogatory to the extent that it is premature as the Court

has not yet issued its claim construction order. Plaintiffs further object to this Interrogatory to the extent it seeks information that will be provided by the Court in its claim construction order.

Plaintiffs further object to this Interrogatory to the extent Defendant seeks to use this Interrogatory to impermissibly advance the timing of Plaintiffs' disclosure of expert discovery and to the extent that this Interrogatory is premature in that fact and expert discovery has not been completed. *Novanta Corp. v. Iridion Laser, Inc.*, 2016 U.S. Dist. LEXIS 126042, at \*22-23 (D. Del. Sept. 16, 2016) ("If the court forces a party to respond to early contention interrogatories, the party may have to set forth theories of its case that have not yet been developed. . . the parties' respective infringement and invalidity theories will advance over the course of that time. [ ] The same holds true for affirmative defenses."); *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93, 96 (E.D. Pa. 1992) (contention interrogatories were premature when filed before substantial documentary or testimonial discovery had been completed). Plaintiffs further object to this Interrogatory to the extent that it seeks a legal conclusion. Plaintiffs further object to this Interrogatory to the extent that it seeks discovery of information that is subject to the attorney-client privilege, work product immunity, and/or any other applicable privilege or immunity.

Plaintiffs will supplement their response to this interrogatory after the Court issues its claim construction decision in accordance with the Federal Rules of Civil Procedure.

**SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 10 (June 13, 2024):**

Plaintiffs incorporate their general and specific objections above. Subject to those objections, Plaintiffs respond further as follows.

Example 6 of the '952 patent falls within the scope of Claim 1 of the '952 patent. The calculated amounts of cyclophosphamide, PEG, ethanol and propylene glycol are within the ranges in claim 1. The use of the term "comprising" in the preamble of Claim 1 allows for the inclusion

of monothioglycerol of Example 6 even though not recited in the Claim. As an inventive formulation, the '952 patent teaches that it has impurities controlled within acceptable limits. Col. 2, ll41-46. In an aspect, when tested for stability after being stored at 40 ° C. , 75 % RH for 7 days, the formulations show less than 0.5 % each of impurities A, B and D, more preferably less than 0.4 % each of impurities A, B and D. Col. 3, ll. 11-18. See also, *e.g.*, ING000030-33; ING000072-73; ING000079-81; ING000085-89; ING000096-100; ING0000147-50; ING0000152-55; ING0000167-70; ING0000213, ING0000232-33, ING0000240-41.

**INTERROGATORY NO. 11:**

If Plaintiffs contend that any example disclosed in the 952 patent other than Example 6 falls within the scope of claim 4 of the 952 patent, explain the complete basis for this contention. If Plaintiffs do not make such a contention, state that Plaintiffs do not contend that an example of the 952 patent other than Example 6 falls within the scope of claim 4.

**RESPONSE TO INTERROGATORY NO. 11 (May 17, 2024):**

In addition to its General Objections, Plaintiffs object to this Interrogatory to the extent that the Interrogatory seeks Plaintiffs' contentions regarding Defendant's invalidity defenses and Plaintiffs' infringement positions before discovery is substantially complete. Plaintiffs have no contention responsive to this interrogatory at this time. Plaintiffs further object to this Interrogatory to the extent that it is premature as the Court has not yet issued its claim construction order. Plaintiffs further object to this Interrogatory to the extent it seeks information that will be provided by the Court in its claim construction order.

Plaintiffs further object to this Interrogatory to the extent Defendant seeks to use this Interrogatory to impermissibly advance the timing of Plaintiffs' disclosure of expert discovery and to the extent that this Interrogatory is premature in that fact and expert discovery has not been



completed. *Novanta Corp. v. Iridion Laser, Inc.*, 2016 U.S. Dist. LEXIS 126042, at \*22-23 (D. Del. Sept. 16, 2016) (“If the court forces a party to respond to early contention interrogatories, the party may have to set forth theories of its case that have not yet been developed. . . the parties’ respective infringement and invalidity theories will advance over the course of that time. [ ] The same holds true for affirmative defenses.”); *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93, 96 (E.D. Pa. 1992) (contention interrogatories were premature when filed before substantial documentary or testimonial discovery had been completed)... Plaintiffs further object to this Interrogatory to the extent that it seeks a legal conclusion. Plaintiffs further object to this Interrogatory to the extent that it seeks discovery of information that is subject to the attorney-client privilege, work product immunity, and/or any other applicable privilege or immunity.

Plaintiffs will supplement their response to this interrogatory after the Court issues its claim construction decision in accordance with the Federal Rules of Civil Procedure.

**SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 11 (June 13, 2024):**

Plaintiffs incorporate their general and specific objections above. Subject to those objections, Plaintiffs respond further as follows.

Example 8 of the ‘952 patent falls within the scope of Claim 4 of the ‘952 patent. The calculated amounts of cyclophosphamide, PEG, ethanol, propylene glycol, and monothioglycerol are all within the ranges of Claim 4. The use of the term “comprising” in the preamble of Claim 4 allows for the inclusion of water in Example 8 even though not recited in the Claim. In addition, the ratio of PEG and propylene glycol in Example 8 is 1.0:1.0 as specified in Claim 4.

**INTERROGATORY NO. 12:**

If Plaintiffs contend that any of the formulations identified in Table 4 of the Declaration of Banda Nagaraju, dated April 8, 2020, is disclosed in the 952 patent, state the complete basis for

this contention. (The Declaration of Banda Nagaraju, dated April 8, 2020, has been produced at ING00000146-150.) If Plaintiffs do not make such a contention, state that Plaintiffs do not contend that any of the formulations identified at Table 4 of the Declaration of Banda Nagaraju, dated April 8, 2020, is disclosed in the 952 patent.

**RESPONSE TO INTERROGATORY NO. 12 (May 17, 2024):**

In addition to its General Objections, Plaintiffs object to this Interrogatory to the extent that the Interrogatory seeks Plaintiffs' contentions regarding its invalidity defenses and infringement positions before discovery is substantially complete. Plaintiffs further object to this Interrogatory to the extent Defendant seeks to use this Interrogatory to impermissibly advance the timing of Plaintiffs' disclosure of expert discovery and to the extent that this Interrogatory is premature in that fact and expert discovery has not been completed. *Novanta Corp. v. Iradion Laser, Inc.*, 2016 U.S. Dist. LEXIS 126042, at \*22-23 (D. Del. Sept. 16, 2016) ("If the court forces a party to respond to early contention interrogatories, the party may have to set forth theories of its case that have not yet been developed. . . the parties' respective infringement and invalidity theories will advance over the course of that time. [ ] The same holds true for affirmative defenses."); *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93, 96 (E.D. Pa. 1992) (contention interrogatories were premature when filed before substantial documentary or testimonial discovery had been completed)... Plaintiffs have no contention responsive to this interrogatory at this time. If Defendant sets forth an invalidity contention directed to "any of the formulations identified in Table 4 of the Declaration of Banda Nagaraju, dated April 8, 2020," Plaintiffs will respond as appropriate in accordance with the case schedule.

Plaintiffs further object to this Interrogatory to the extent that it seeks discovery of information that is subject to the attorney-client privilege, work product immunity, and/or any

other applicable privilege or immunity.

Plaintiffs further object to this Interrogatory the extent that it is premature as the Court has not yet issued its claim construction order. Plaintiffs further object to this Interrogatory to the extent it seeks information that will be provided by the Court in its claim construction order.

Plaintiffs object to this Interrogatory to the extent it seeks information that is equally accessible and burdensome for Defendant to access and assess.

Subject to the foregoing General and Specific Objections, Plaintiffs respond that the formulations identified in Table 4 of the Declaration of Banda Nagaraju, dated April 8, 2020 (ING00000146-150) list concentrations (in weight percent) of ethanol, PG and PEG that are disclosed in the '952 patent at least at Col. 2, ll 51-58; Col. 2, l. 59-Col. 4, l. 5.

**SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 12 (June 13, 2024):**

Plaintiffs incorporate their general and specific objections above. Subject to those objections, Plaintiffs respond further as follows.

The April 8, 2020 Declaration and the data contained in Table 4 therein is dated more than five years after the foreign priority application containing the formulations disclosed in the '952 Patent was filed. Plaintiffs have not formulated any contentions one way or the other regarding the data in Table 4 of the April 8, 2020 Declaration as it relates to the formulations disclosed in the '952 Patent. Plaintiffs may supplement their response to this Interrogatory, as appropriate, upon the development of further discovery. *Novanta Corp.* 2016 U.S. Dist. LEXIS at \*22-23 (D. Del. Sept. 2016) (declining to force parties to respond to contention interrogatories before its theories of its case have been developed).

Dated: June 13, 2024

**SMITH, KATZENSTEIN & JENKINS LLP**

/s/ Roman Rachuba

*Of Counsel:*

Michael Dzwonczyk  
John T. Callahan  
Chidambaram S. Iyer  
L. Roman Rachuba

**SUGHRUE MION PLLC**

2000 Pennsylvania Ave., N.W., Suite 900  
Washington, D.C. 20006  
(973) 998-7722  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860  
mdzwonczyk@sughrue.com  
jcallahan@sughrue.com  
ciyer@sughrue.com  
lrachuba@sughrue.com

*Delaware Counsel:*

Neal C. Belgam (No. 2721)  
Daniel A. Taylor (No. 6934)  
1000 West Street, Suite 1501  
Wilmington, DE 19801  
(302) 652-8400  
nbelgam@skjlaw.com  
dtaylor@skjlaw.com

*Counsel for Plaintiffs Ingenus  
Pharmaceuticals, LLC, and Leiutis  
Pharmaceuticals LLP*

**CERTIFICATE OF SERVICE**

I hereby certify that on June 13, 2024, true and correct copies of the foregoing document were caused to be served on the following counsel of record as indicated:

**VIA EMAIL**

Benjamin J. Schladweiler  
Renée Mosley Delcollo  
222 Delaware Avenue, Suite 1600  
Wilmington, DE 19801  
(302) 661-7000  
schladweilerb@gtlaw.com  
renee.delcollo@gtlaw.com  
Attorneys for Defendant Accord  
Healthcare, Inc.

**VIA EMAIL**

Alejandro Menchaca  
Rajendra A. Chiplunkar  
Ben J. Mahon  
Bradley P. Loren  
MCANDREWS, HELD & MALLOY,  
LTD.  
500 West Madison St., 34th Floor  
Chicago, IL 60661  
(312) 775-8000  
amenchaca@mcandrews-ip.com  
rchiplunkar@mcandrews-ip.com  
bmahon@mcandrews-ip.com  
bloren@mcandrews-ip.com

s/ Luke Cooper /

# EXHIBIT C

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC,  
and LEIUTIS PHARMACEUTICALS LLP,

Plaintiffs,

v.

ACCORD HEALTHCARE, INC.,

Defendant.

C.A. No. 23-377-CFC

**ANDA CASE**

**PLAINTIFFS' RESPONSES TO DEFENDANT'S FIRST SET OF REQUESTS FOR  
PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1-25)**

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, and the Local Rules of this Court, Plaintiffs Ingenus Pharmaceuticals, LLC and Leiutis Pharmaceuticals LLP ("Plaintiffs") hereby respond to the First Set of Requests for Production of Documents and Things (Nos. 1-25) (hereinafter "Requests") served by Accord Healthcare, Inc., ("Defendant" or "Accord") as follows:

**RESPONSES AND OBJECTIONS**

The following general objections ("General Objections") are incorporated into each specific response and objection as if fully set forth therein:

1. Plaintiffs' responses are made to the best of their present knowledge, information, and belief. Plaintiffs' investigation of the facts is ongoing, and Plaintiffs reserve the right to supplement or amend the responses pursuant to the Federal Rules of Civil Procedure, the local rules, and any scheduling order entered in this case.

2. Plaintiffs' object to the Requests to the extent they request information or documents related to Plaintiffs' drug products other than the drug product of New Drug Application ("NDA") No. 212501, cyclophosphamide for injection.

3. Plaintiffs object to the Requests' definitions of "Patent-in-Suit", "Related Patents and Applications", and "Foreign Counterpart" to the extent they includes patents that are not at issue in this litigation.

4. Plaintiffs object to the Requests, Definitions and Instructions to the extent that they call for the production of documents outside Plaintiffs' possession, custody or control; to prepare information or documents that do not already exist; or to produce documents or information in a format other than that in which it is ordinarily kept by Plaintiffs. Plaintiffs will produce responsive documents to the extent that they exist—after performing a reasonable search proportional to the needs of the case. Nothing contained in any response herein shall be deemed an admission that any responsive documents exist.

5. Plaintiffs object to the Requests' Definitions and Instructions to the extent they require Plaintiffs to use search terms to locate potentially responsive Electronically Stored Information (ESI) or to produce ESI in a manner that is not proportional to the needs of the case, such as methods other than those described in Paragraph 5 of the Court's Default Standard for Electronic Discovery.

6. Plaintiffs object to the Requests, Definitions and Instructions to the extent that they contain express or implied assumptions of fact or law with respect to matters at issue in this action. Plaintiffs' responses and objections to the Requests are not intended to be, and shall not be construed as, an agreement or concurrence by Plaintiffs with Accord's characterization of any



facts, circumstances, and/or legal obligations. Plaintiffs also reserve the right to contest any such characterization as inaccurate.

7. To the extent that any Request calls for “all,” “each,” or “every” document(s), Plaintiffs object to each Request as being overly broad and unduly burdensome. It is impossible to represent, even after a reasonable and diligent search, that all, each, or every document or piece of information falling within a description can be or has been assembled. Plaintiffs will produce documents within their possession, custody, and control that can be located after a reasonable search that is proportional to the needs of the case.

8. Plaintiffs will produce relevant, non-privileged documents on a rolling basis in response to the Requests, subject to and without waiver of the Objections stated herein. The term “non-privileged documents” as used herein refers to documents or information that is not subject to the attorney-client privilege, does not constitute attorney work product, and is not otherwise privileged or exempt from discovery.

9. Plaintiffs provide these Responses and Objections subject to further investigation. Plaintiffs reserve the right to modify, supplement or amend any or all of these Responses and Objections, if necessary or appropriate, and to produce additional, non-privileged, responsive documents if any are located.

10. Plaintiffs object to each and every Request to the extent that the Request, Definitions and/or Instructions, individually and/or collectively, seek to impose requirements or obligations on Plaintiffs in addition to or different from those imposed by law, the Federal Rules of Civil Procedure, or the applicable local rules.

11. Plaintiffs object to each and every Request to the extent that the Request seeks production of materials subject to a third party confidentiality agreement between Plaintiffs on the

one hand and another party on the other hand, or to the extent that the Request seeks production of materials with respect to which the consent of any third party or any governmental officer or agency must be obtained prior to its disclosure.

12. Plaintiffs object to each and every Request to the extent that the Request seeks documents and things not in the possession, custody or control of Plaintiffs. Further, Plaintiffs object to these Requests to the extent that they seek documents and things from entities or individuals not a party to this litigation, which are not in the possession, custody, or control of Plaintiffs.

13. To the extent that each Request calls for the production of proprietary and confidential business information, Plaintiffs' production of documents and things containing proprietary and confidential business information are subject to any protective order entered by the Court in this case and shall be restricted to outside attorneys only.

14. Plaintiffs object to each Request to the extent it purports to require Plaintiffs to search for and/or produce "any" and "all" documents and things. Consistent with its obligations under the Federal Rules of Civil Procedure and subject to its objections, Plaintiffs will produce responsive, non-privileged documents and things to the extent such materials exist and are located after a reasonable search of its files.

15. To the extent that Plaintiffs provide documents and things in response to the requests, Plaintiffs do not concede that the documents or things provided are relevant to this action or any issue properly raised. Plaintiffs expressly reserve the right to object to further discovery into the subject matter of such Requests and the introduction into evidence of any document, thing, or portion thereof.

16. Plaintiffs object to the definition of “Plaintiffs,” “Ingenus,” “You” and “Your” in the Definitions as being overly broad, unduly burdensome and oppressive, on the grounds that it includes undefined and/or non-existent entities, such as predecessors, successors, present and former partners, investors, corporate parents, affiliated companies or corporations, direct or indirect subsidiaries, officers, directors, employees, agents, attorneys, servants, representatives, and all other persons acting, or purporting to act, on its or their behalf” and purports to include entities that are not named parties to the case.

17. Plaintiffs incorporate by reference their General Objections in each of the specific responses set forth below.

### **SPECIFIC RESPONSES AND OBJECTIONS**

#### **REQUEST FOR PRODUCTION NO. 1**

All documents and things concerning Your New Drug Application No. 212501, including the full and complete NDA, all documents and things submitted to the FDA in connection with Your NDA, and all documents and things concerning the preparation of Your NDA.

#### **RESPONSE**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks “[a]ll documents and things concerning” as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things concerning” as

requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs additionally object to this Request to the extent that it calls for information that is not within the possession, custody, or control of Plaintiffs.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

#### **REQUEST FOR PRODUCTION NO. 2**

All documents and things concerning any supplements or amendments to Your New Drug Application No. 212501, including the full and complete supplements and amendments to Your NDA, and all related communications or correspondence with the FDA or any other person or entity.

#### **RESPONSE**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks "[a]ll documents and things concerning" as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and

cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things concerning” as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs additionally object to this Request to the extent that it calls for information that is not within the possession, custody, or control of Plaintiffs.

Plaintiffs additionally object to this Request to the extent that it seeks discovery that would result in violation of Plaintiffs’ obligations of confidentiality to third parties.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

### **REQUEST FOR PRODUCTION NO. 3**

All documents and things concerning any communications, including confidential communications to or from the FDA, concerning Your New Drug Application No. 212501.

### **RESPONSE**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party’s claims or defenses.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks “[a]ll documents and things concerning” as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things concerning” as

requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs additionally object to this Request to the extent that it calls for information that is not within the possession, custody, or control of Plaintiffs.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

#### **REQUEST FOR PRODUCTION NO. 4**

All communications between You and any third party, including, without limitation the, FDA, materials and/or ingredient suppliers, and/or any collaborative partners, concerning, referring, or relating to Your New Drug Application No. 212501, Your cyclophosphamide product, the API used in Your cyclophosphamide product, the Patent-in-Suit, and/or Accord's ANDA No. 218250.

#### **RESPONSE**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs additionally object to this Request to the extent that it calls for information that is not within the possession, custody, or control of Plaintiffs.

Plaintiffs additionally object to this Request because the term "Your cyclophosphamide product" is vague and undefined.

Plaintiffs additionally object to this Request to the extent that it seeks discovery that would result in violation of Plaintiffs' obligations of confidentiality to third parties.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

#### **REQUEST FOR PRODUCTION NO. 5**

All documents and things concerning Your decision to prepare and file Your New Drug Application No. 212501.

#### **RESPONSE**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks "[a]ll documents and things concerning" as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify "[a]ll documents and things concerning" as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 6**

All documents and things, including lab notebooks and summary reports, concerning any chemical or physical stability testing of Your cyclophosphamide product conducted by or for You or Your manufacturers and suppliers.

**RESPONSE:**

In addition to the General Objections, Plaintiffs further object to this Request because the term “Your cyclophosphamide product” is vague and undefined.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks “[a]ll documents and things” as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things” as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Subject to and without waiving the foregoing General Objections and specific objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search of their files.

**REQUEST FOR PRODUCTION NO. 7**

All documents and things concerning any communications, including confidential communications to or from the FDA, concerning Your cyclophosphamide product.

**RESPONSE:**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).



Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs additionally object to this Request because the term "Your cyclophosphamide product" is vague and undefined.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks "[a]ll documents and things concerning" as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify "[a]ll documents and things concerning" as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs additionally object to this Request to the extent that it calls for information that is not within the possession, custody, or control of Plaintiffs.

Plaintiffs additionally object to this Request to the extent that it is duplicative in view of Request No. 3.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

#### **REQUEST FOR PRODUCTION NO. 8**

All documents and things concerning, relied upon, or used in the preparation of Your complaint, D.I. 1, filed in this civil action.

**RESPONSE:**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs additionally object to this Request to the extent that it calls for information that is not within the possession, custody, or control of Plaintiffs.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks "[a]ll documents and things concerning" as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify "[a]ll documents and things concerning" as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 9**

All documents and things concerning, referred to, relied upon, or used in the preparation of Your Initial Disclosures pursuant to Rule 26(a)(1) of the Federal Rules of Civil Procedure in connection with this litigation, including all discoverable information of all individuals identified by You therein.

**RESPONSE:**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks "[a]ll documents and things concerning" as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify "[a]ll documents and things concerning" as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs additionally object to this Request to the extent that it calls for information that is not within the possession, custody, or control of Plaintiffs.

Plaintiffs additionally object to this request to the extent the phrase "all discoverable information of all individuals" is overly broad and unduly burdensome.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 10**

All documents and things concerning, related to, or evidencing the inventions disclosed and/or claimed in the Patent-in-suit.

**RESPONSE:**

In addition to the General Objections Plaintiffs further object to this Request to the extent the phrase “[a]ll documents and things concerning, related to, or evidencing the inventions” is overly broad and unduly burdensome, and unintelligible as written.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks “[a]ll documents and things concerning” as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things concerning” as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party’s claims or defenses.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 11**

All documents and things concerning the design, formulation, and manufacture of Your cyclophosphamide product, including any work done to develop the formulation, packaging, labeling, any and all associated processing methods, and manufacturing steps used to make Your cyclophosphamide product.

**RESPONSE:**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks "[a]ll documents and things concerning" as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify "[a]ll documents and things concerning" as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs additionally object to this Request because the term "Your cyclophosphamide product" is vague and undefined.

Plaintiffs additionally object to this Request to the extent that it calls for information that is not within the possession, custody, or control of Plaintiffs.

Plaintiffs additionally object to this Request to the extent that it seeks discovery that would result in violation of Plaintiffs' obligations of confidentiality to third parties.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 12**

All documents and things concerning the excipients and/or solvents used in Your cyclophosphamide product, or in any formulation containing cyclophosphamide that You considered, tested, evaluated, or proposed for submission to the FDA, in connection with the development of Your cyclophosphamide product.

**RESPONSE:**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks "[a]ll documents and things concerning" as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify "[a]ll documents and things concerning" as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs additionally object to this Request because the term "Your cyclophosphamide product" is vague and undefined.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 13**

All documents and things concerning all analytical testing of Your cyclophosphamide product or the API used in Your cyclophosphamide product or of any formulation containing cyclophosphamide that You considered, tested, evaluated, or proposed for submission to the FDA, in connection with the development of Your cyclophosphamide product, including any formulation that was abandoned or was not selected as Your final formulation.

**RESPONSE:**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks "[a]ll documents and things concerning" as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify "[a]ll documents and things concerning" as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs additionally object to this Request because the term "Your cyclophosphamide product" is vague and undefined.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 14**

All documents and things concerning any formulation containing cyclophosphamide that You considered, tested, evaluated, or proposed for submission to the FDA, in connection with the development of Your cyclophosphamide product, including the manufacturing processes used to produce each, batch records for each, and testing of each.

**RESPONSE:**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks “[a]ll documents and things concerning” as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things concerning” as requested.

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party’s claims or defenses.

Plaintiffs additionally object to this Request because the term “Your cyclophosphamide product” is vague and undefined.

Plaintiffs additionally object to this Request to the extent that it seeks discovery that would result in violation of Plaintiffs’ obligations of confidentiality to third parties

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.



**REQUEST FOR PRODUCTION NO. 15**

All documents and things concerning the stability of Your cyclophosphamide product, including, but not limited to, all documents concerning the conversion of cyclophosphamide to

- a) bis(2-chloroethyl)amine hydrochloride;
- b) 3-(2-chloroethyl)-2-oxo-2-hydroxy-1,3,6,2-oxadiazaphosphonane; and
- c) 3-[2-(2-chloroethylamino)ethyl amino] propyl dihydrogen phosphate dihydrochloride.

**RESPONSE:**

In addition to the General Objections Plaintiffs further object to this Request to the extent that it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks "[a]ll documents and things concerning" as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify "[a]ll documents and things concerning" as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs additionally object to this Request because the term "Your cyclophosphamide product" is vague and undefined.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 16**

All documents and things that concern, support, or refute any objective indicia of non-obviousness, including commercial success, long-felt need, skepticism, industry recognition, unexpected results, and copying of the claimed subject matters of the Patent-in-suit.

**RESPONSE:**

In addition to the general objections, Plaintiffs further object to this Request as not relevant to the claim or defense of any party, and as not proportional to the needs of this case, for example, to the extent it is unbounded as to time, and the burden and expense to Plaintiffs in responding to this Request outweighs any likely benefit to Defendant.

Plaintiffs further object to this Request as premature on the basis that it seeks information relating to defenses not yet raised by Defendant. Plaintiffs further object to this Request as premature on the basis that it seeks information that is the subject of expert disclosures and/or testimony. Plaintiffs object to this Request as seeking information beyond the requirements of Federal Rule of Civil Procedure 26.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks “[a]ll documents and things that concern” as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things that concern” as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs further object to this Request as premature under the Scheduling Order in this case, including to the extent it prematurely seeks expert opinion(s) and supporting materials prior to the schedule stipulated by the parties and ordered by the Court. (D.I. 18).

Plaintiffs further object to this Request as calling for a disputed legal conclusion. Plaintiffs object to this Request to the extent the information requested therein is not within the possession, custody and/or control of Plaintiffs.

Plaintiffs further object to this Request to the extent it seeks information protected from disclosure by the attorney-client privilege, work product immunity, common interest, or any other applicable privilege or protection.

Subject to and without waiving the foregoing objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 17**

Produce all prior art concerning the stability of cyclophosphamide formulations, including but not limited to the conversion of cyclophosphamide to

- a) bis(2-chloroethyl)amine hydrochloride;
- b) 3-(2-chloroethyl)-2-oxo-2-hydroxy-1,3,6,2-oxadiazaphosphonane; and
- c) 3-[2-(2-chloroethylamino)ethyl amino] propyl dihydrogen phosphate dihydrochloride.

**RESPONSE:**

In addition to the General Objections, Plaintiffs further object to this Request to the extent it calls for information not within Plaintiffs' possession, custody, or control.

Plaintiffs further object to this request to the extent it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs further object to this request to the extent the phrase "all prior art concerning the stability of cyclophosphamide formulations" is overly broad and unduly burdensome. The burden and expense to Plaintiffs in responding to this Request outweighs any likely benefit to Defendant.

Plaintiffs further object to this Request to the extent the information is equally accessible to Defendant.

Plaintiffs further object to this Request because it is duplicative in view of Request No. 15.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 18**

All documents, communications, and things concerning any prior art to the Patent-in-suit (whether or not such prior art was disclosed to the PTO), including, without limitation: (i) any prior art identified during any prior-art search conducted by you or on your behalf; (ii) any prior art identified or made known to you by any third party; (iii) all internal documents and communications concerning any prior art identified or made known to you; (iv) references submitted to the PTO during prosecution of the applications that ultimately issued as the Patent-in-Suit; and (v) references cited, discussed, or otherwise disclosed in the specification of the Patent-in-Suit.

**RESPONSE:**

In addition to the General Objections, Plaintiffs further object to this Request to the extent it calls for information not within Plaintiffs' possession, custody, or control.

Plaintiffs further object to this Request to the extent the phrase "[a]ll documents, communications, and things concerning any prior art to the Patent-in-suit" is overly broad and unduly burdensome. The burden and expense to Plaintiffs in responding to this Request outweighs any likely benefit to Defendant.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks “[a]ll documents and things concerning” as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things concerning” as requested.

Plaintiffs further object to this Request to the extent the information is equally accessible to Defendant.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 19**

All documents and things concerning the conception, reduction to practice, inventorship, research, development, applications, or uses of the alleged inventions claimed in the Patent-in-suit, including, but not limited to, all documents and things concerning any or all of the following:

- the first conception of each of the alleged inventions;
- the first reduction to practice of each of the alleged inventions;
- the inventors’ diligence in reducing each of the alleged inventions to practice from the date of the first conception to the date of first actual or constructive reduction to practice;
- the contribution of any of the Named Inventors of the Patent-in-suit and any other individuals to any alleged invention;
- the identity of the individual(s) who allegedly conceived of, and/or reduced to practice or assisted in the reduction to practice of, the alleged inventions;

- the project initiation of the alleged inventions (including Your cyclophosphamide product or any other alleged commercial embodiment); and
- the diligence towards making a physical embodiment of the alleged inventions (including Your cyclophosphamide product or any other alleged commercial embodiment).

This request includes, without limitation, laboratory notebooks, invention disclosures, invention records, notes, calendars, publications, manuscripts, abstracts, posters, descriptions, reports, protocols, studies, results, data, memoranda, reports, agendas, meeting minutes, presentations, files, emails, electronic records, analyses, and summaries of the Named Inventors of the Patent-in-suit, or any person working in collaboration with or under the direction of any of the Named Inventors of the Patent-in-Suit, or any person under whose direction any of the Named Inventors of the Patent-in-Suit was working, that concern the subject matter of the Patent-in-Suit.

**RESPONSE:**

In addition to the General Objections, Plaintiffs further object to this Request as improperly calling for a legal conclusion.

Plaintiffs further object to this Request to the extent it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks “[a]ll documents and things concerning” as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things concerning” as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs object to this Request as seeking information beyond the requirements of Federal Rule of Civil Procedure 26.

Plaintiffs additionally object to this Request because the term “Your cyclophosphamide product” is vague and undefined.

Plaintiffs further object to this Request to the extent it calls for information that is not relevant to any Party’s claims or defenses.

Plaintiffs further object to this Request to the extent the information is equally accessible to Defendant.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 20**

All documents, communications, and things referring to or concerning any example, test, experiment, analytical technique, data, and/or information referenced in the Patent-in-suit, and the results obtained from those tests and/or experiments, including, without limitation, all laboratory notebook entries, reports, memoranda, analyses, meeting minutes, datasets, test data, and records and analyses of clinical data related thereto, as well as all information regarding the instrumentation used to carry out such testing and/or experimentation.

**RESPONSE:**

In addition to the General Objections, Plaintiffs further object to this Request to the extent it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks “[a]ll documents and things concerning” as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things concerning” as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Plaintiffs further object to this Request to the extent it calls for information that is not within Plaintiffs’ possession, custody, or control.

Plaintiffs further object to this Request to the extent it calls for information that is not relevant to any Party’s claims or defenses.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

#### **REQUEST FOR PRODUCTION NO. 21**

All documents, communications, and things constituting, referring, or relating to the first disclosure, first publication, first use, first offer for sale, and/or first sale of the subject matter claimed in the Patent-in-suit, including, without limitation, any product or thing covered by any claim of any of the Patent-in-suit.

#### **RESPONSE:**

In addition to the General Objections, Plaintiffs further object to this Request to the extent it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).



Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks “[a]ll documents, communications, and things concerning” as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things concerning” as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 22**

All documents, communications, and things concerning the Patent-in-suit and/or any Related Patents and Applications, including, without limitation, all documents and communications concerning any or all of the following:

- The patentability or validity of any alleged invention or subject matter claimed or disclosed therein, including all correspondence, memoranda, presentations, studies, prior-art searches, the results of any prior-art searches, and any report based on the prior-art searches; as well as all publications, patents, things, public uses, and offers for sale located or identified in connection with any investigation regarding the patentability or validity;
- All publications, patents, things, public uses, and offers for sale located or identified in connection with any investigation regarding the patentability or validity;
- Any opposition (including oppositions to Foreign Counterparts), litigation, reissues, reexaminations, inter partes review, post grant reviews, interferences, patent term extension, or

any other proceedings relating to the validity, enforceability, infringement, and/or extension of the Patent-in-Suit;

- Your purchase, licensing, and/or acquisition of any ownership interest in or other rights to the Patent-in-Suit, including documents sufficient to show the current ownership of the Patent-in-Suit, documents sufficient to identify all persons involved in the acquisition of any interest in or other rights to the Patent-in-Suit by Plaintiffs, and documents and communications concerning any due diligence performed with respect to such acquisition, including any valuations of the Patent-in-Suit; and

- Any memoranda of invention or equivalent documents relating to the Patent-in-Suit.

**RESPONSE:**

In addition to the General Objections, Plaintiffs further object to this Request to the extent it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs further object to this Request to the extent that it calls for information that is not relevant to any Party's claims or defenses.

Plaintiffs further object to this Request to the extent it calls for information not within Plaintiffs' possession, custody, or control.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks "[a]ll documents, communications, and things concerning" as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify "[a]ll documents and things concerning" as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 23**

All documents and things referring or relating to the prosecution of the Patent-in-suit, Related Patents and Applications, and/or Foreign Counterparts, including, without limitation:

- The complete prosecution histories for each of the Patent-in-Suit, any Related Patents and Applications, and any Foreign Counterparts, including any reexamination, reissue, opposition, or cancellation proceedings;
- The preparation of the applications that resulted in the Patent-in-Suit, any Related Patents and Applications, or any Foreign Counterparts, including all documents reviewed, considered, provide any part of the basis for, relied upon, or referenced by the patent attorney(s) or agent(s), Named Inventors, or anyone else involved in preparing such applications;
- The prosecution of the applications that resulted in the Patent-in-Suit, Related Patents and Applications, and/or Foreign Counterparts, including all applications, documents, and communications sent to or received from any third party, including the PTO, the Named Inventors, any patent agent or attorney, any prior-art researcher, and any person who authored any declarations submitted to the PTO;
- All draft patent applications leading to the Patent-in-suit and all draft papers filed during prosecution of the Patent-in-suit;
- All documents and things sufficient to identify all persons involved in any decisions or discussions relating to whether to seek patent claims covering the subject matter of any of the

claims of the Patent-in-Suit, including any communications between you and the Named Inventors or any attorney for you and the Named Inventors; and

- Any declarations that were submitted to the PTO during prosecution of the Patent-in-Suit or any Related Patents and Applications.

**RESPONSE:**

In addition to the General Objections, Plaintiffs further object to this Request to the extent it calls for information protected by attorney-client privilege, work-product doctrine and/or any other protection afforded by Fed. R. Civ. P. 26(b).

Plaintiffs additionally object to this Request to the extent the information requested is equally accessible to Defendant.

Plaintiffs additionally object to this Request as overly broad and unduly burdensome on the grounds that it seeks “[a]ll documents and things concerning” as such a request encompasses unreasonably duplicative and cumulative documents that unnecessarily increase the burden and cost of this case. Plaintiffs cannot possibly identify “[a]ll documents and things concerning” as requested. The benefit of such overly broad discovery is completely outweighed by the burden it imposes.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

**REQUEST FOR PRODUCTION NO. 24**

All documents that you contend evince the skills and/or qualifications of a person of ordinary skill in the art pertaining to the Patent-in-suit, including, without limitation, (i) the educational level of the Named Inventors; (ii) the type of problems encountered in the art; (iii) the

prior art solutions to those problems; (iv) the rapidity with which innovations are made; (v) the sophistication of the technology; and (vi) the educational level of active workers in the field.

**RESPONSE:**

In addition to the General Objections, Plaintiffs object to this Request to the extent it calls for information protected by attorney-client privilege, work-product doctrine or any other protection or immunity rendering information immune from discovery.

Plaintiffs further object to this Request as premature on the basis that it seeks information that is the subject of expert disclosures and/or testimony. Plaintiffs object to this Request as seeking information beyond the requirements of Federal Rule of Civil Procedure 26. Plaintiffs object to this Request as premature under the Scheduling Order in this case (D.I. 18), including to the extent it prematurely seeks expert opinion(s) and supporting materials. Plaintiffs object to this Request as calling for a legal conclusion. Plaintiffs object to this Request to the extent the information requested therein is not within the possession, custody and/or control of Plaintiffs.

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search of their files that concern Plaintiffs' assertion of a definition of a person of ordinary skill in the art in accordance with the Court's scheduling order.

**REQUEST FOR PRODUCTION NO. 25**

The current *curriculum vitae*, resume, biography, or equivalent document for each Named Inventor, individuals identified in Plaintiffs' disclosures under Fed. R. Civ. Pro. 26(a), and expert(s) for Plaintiffs.

**RESPONSE:**

Subject to and without waiving the foregoing General Objections, Plaintiffs will produce relevant, responsive, non-privileged documents within their possession, custody or control, that can be obtained upon a reasonable search, in response to this Request.

Dated: December 1, 2023

**SMITH, KATZENSTEIN & JENKINS LLP**

*Of Counsel:*

Michael Dzwonczyk  
John T. Callahan  
Chidambaram S. Iyer  
L. Roman Rachuba  
**SUGHRUE MION PLLC**  
2000 Pennsylvania Ave., N.W., Suite 900  
Washington, D.C. 20006  
(973) 998-7722  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860  
mdzwonczyk@sughrue.com  
jcallahan@sughrue.com  
ciyer@sughrue.com  
lrachuba@sughrue.com

/s/ Daniel A. Taylor

Neal C. Belgam (No. 2721)  
Daniel A. Taylor (No. 6934)  
1000 West Street, Suite 1501  
Wilmington, DE 19801  
(302) 652-8400  
nbelgam@skjlaw.com  
dtaylor@skjlaw.com

*Counsel for Plaintiffs Ingenus  
Pharmaceuticals, LLC, and Leiutis  
Pharmaceuticals LLP*

# EXHIBIT D

## Alex Menchaca

---

**From:** Alex Menchaca  
**Sent:** Wednesday, June 12, 2024 9:29 AM  
**To:** 'Hur, Soo Jin'; Dzwonczyk, Michael R.; Iyer, Chid S.; Callahan, John T.; Rachuba, L Roman; nbelgam; Daniel A. Taylor; mdaughton@skjlaw.com; Cooper, Luke W.  
**Cc:** Ben J. Mahon; Brad P. Loren; Rajendra A. Chiplunkar; 'schladweilerb@gtlaw.com'; 'Renee.Delcollo@gtlaw.com'  
**Subject:** RE: Ingenus v. Accord -- deficient discovery responses

Counsel,

Having received no response to the below email, please advise of Plaintiffs availability Thursday, June 13 or Tuesday, June 18, 2024 for a meet and confer regarding the issues raised in the below email. **Of particular interest, Plaintiffs must advise of their intent to supplement the interrogatory responses and for which responses Plaintiffs will stand on their current response and make no supplement.**

At that meet and confer, Accord also intends to address deficiencies in Plaintiffs responses to requests to admit. Plaintiffs objections are not supported. For example, Plaintiffs object to the term "stability data," but that term is used in the patent in suit. Also, a number of responses appear to be in bad faith. For example, all of the asserted claims require both polyethylene glycol and propylene glycol. Example 3 has no polyethylene glycol. Examples 4 and 5 have no propylene glycol. Yet, when asked to admit that the formulations of examples 3, 4, and 5 do not fall within the scope of any claim of the 952 patent, Plaintiffs denied those requests. Further, to a number of requests to admit Plaintiffs objected that the appropriate discovery mechanism was through other discovery requests, in particular, Interrogatory No. 7. As noted in my email of May 30, 2024, however, in response to interrogatory no. 7, Plaintiffs identified the entire prosecution history of the patent in suit pursuant to Rule 33(d). As noted in the below email, Plaintiffs response to interrogatory no. 7 is improper for at least two reasons – relying on Rule 33(d) and then not specifying the documents from which the information can be ascertained.

I look forward to chatting with you regarding these issues.

Best regards,  
Alex.

  
**McAndrews**  
Alejandro Menchaca  
Attorney at Law  
McAndrews, Held & Malloy, Ltd.  
500 W. Madison St., 34th Floor | Chicago, IL 60661  
P: 312-775-8103  
[amenchaca@mcandrews-ip.com](mailto:amenchaca@mcandrews-ip.com)  
[bio](#) | [v-card](#) | [website](#)

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**From:** Alex Menchaca <AMENCHACA@mcandrews-ip.com>

**Sent:** Thursday, May 30, 2024 4:30 PM

**To:** 'Hur, Soo Jin' <shur@sughrue.com>; Dzwonczyk, Michael R. <mdzwonczyk@sughrue.com>; Iyer, Chid S. <ciyer@sughrue.com>; Callahan, John T. <Jcallahan@sughrue.com>; Rachuba, L Roman <lrachuba@sughrue.com>; nbelgam <nbelgam@skjlaw.com>; Daniel A. Taylor <DAT@skjlaw.com>; mdaughton@skjlaw.com; Cooper, Luke W. <lcooper@sughrue.com>

**Cc:** Ben J. Mahon <BMahon@mcandrews-ip.com>; Brad P. Loren <BLoren@mcandrews-ip.com>; Rajendra A. Chiplunkar <RChiplunkar@mcandrews-ip.com>; 'schladweilerb@gtlaw.com' <schladweilerb@gtlaw.com>; 'Renee.Delcollo@gtlaw.com' <Renee.Delcollo@gtlaw.com>

**Subject:** Ingenus v. Accord -- deficient discovery responses

Counsel,

Regarding Plaintiffs' responses to interrogatories, Plaintiffs have indicated in a number of their responses that they reserve the right to supplement.

Please confirm that Plaintiffs will supplement by June 15, 2024 any responses Plaintiffs intend to supplement.

Additionally, for a number of interrogatory responses, Plaintiffs have relied on Rule 33(d) and designated the entire prosecution history for the patent in suit. See, e.g., responses to interrogatories nos. 3, 5, 7, 9.

Such wholesale designation is improper. Rule 33(d) requires the responding party to "specify[] the records that must be reviewed, in sufficient detail to enable the interrogating party to locate and identify them as readily as the responding party could."

Please confirm that Plaintiffs will supplement by June 15, 2024 their responses to properly specify the records within the prosecution history on which Plaintiffs rely in their interrogatory responses.

Regarding Plaintiffs' response to interrogatories nos. 10 and 11, Plaintiffs agree to supplement the responses after the court issues its claim construction decision.

As Plaintiffs are aware (and were aware when they served their interrogatory response), the court has declined to provide a claim construction decision and instead "will hear the indefinite defense(s) at the bench trial." D.I. 37.

Please confirm that Plaintiffs will supplement by June 15, 2024 their responses to interrogatories nos. 10 and 11.

Regarding contention interrogatories, Plaintiff objects to responding to many interrogatories because they seek Plaintiffs' contentions. Of course, at this stage of the litigation that is not a proper objection. *Corning Optical Commc'ns Wireless Ltd. v. Solid, Inc.*, 306 F.R.D. 276, 278–79 (N.D. Cal. 2015) (rejected a plaintiff's interrogatory response that essentially amounted to, "wait until we serve our expert report."); *Thorn EMI N. Am., Inc. v. Intel Corp.*, 936 F. Supp. 1186, 1191 (D. Del. 1996) (encouraging the use of contention interrogatories to provide "sufficient notice of the opposing party's contentions at trial and an opportunity to respond to those contentions"). Relying on Rule 33(d) in response to contention interrogatories, as Plaintiffs have done in responses to interrogatories nos. 7 and 9, is also not proper. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, Nos. 09-cv-2118 and 08-cv-889, 2013 WL 12291705, at \*1; *SEC v. Elfindapan*, 206 F.R.D. 574, 577 (M.D.N.C. 2002) (noting that contention interrogatories "do not lend themselves to answer by use of Rule 33(d)"); *A.R. v. Dudek*, No. 12-cv-60460, 2015 WL 11143084, at \*4 (S.D. Fla. Oct. 9, 2015) ("[T]he utilization of Rule 33(d) to respond to contention interrogatories is inappropriate for various reasons."); *Culp v. Reed*, No. 1:19-CV-00106, 2021 WL 1341256, at \*3 (N.D. Ind. Apr. 8, 2021) ("In any event, Rule 33(d) does not apply to contention interrogatories . . .") (internal quotation marks and citation omitted).

Please confirm that Plaintiffs will serve proper responses to the contention interrogatories.

In response to interrogatory no. 13, Plaintiffs stated "the Declaration of Kocherlakota Chandrashekhar, dated January 14, 2021 was not produced at ING00000085-89." ING00000085-89 is attached and it is the Declaration of Kocherlakota

Chandrashekhar, dated January 14, 2021. Please advise if this understanding is not correct. Further, as with many of the other contention interrogatories, Plaintiffs failed to respond to the issue of the interrogatory. Please confirm that plaintiffs will respond to interrogatory no. 13, and the other contention interrogatories, as posed.

Best regards,  
Alex.



**McAndrews**

**Alejandro Menchaca**

**Attorney at Law**

McAndrews, Held & Malloy, Ltd.

500 W. Madison St., 34th Floor | Chicago, IL 60661

P: 312-775-8103

[amenchaca@mcandrews-ip.com](mailto:amenchaca@mcandrews-ip.com)

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# **EXHIBIT E**

**From:** Rachuba, L Roman <lrachuba@sughrue.com>  
**Sent:** Tuesday, October 29, 2024 4:40 PM  
**To:** Alex Menchaca; Cooper, Luke W.; 'Morgan M. Daughton'; Ben J. Mahon; 'Benjamin J. Schladweiler'; Brad P. Loren; Rajendra A. Chiplunkar; 'Renee Mosley-Delcollo'  
**Cc:** Iyer, Chid S.; 'Daniel A. Taylor'; Callahan, John T.; Dzwonczyk, Michael R.; 'Neal C. Belgam'; Electronic Case Mgmt  
**Subject:** RE: Case 1:23-cv-00377-CFC, Ingenus Pharmaceuticals, LLC, et al. v. Accord Healthcare, Inc.

**CAUTION: External Email From: lrachuba@sughrue.com**

Alex, that document (as well as the one produced today) is responsive to at least Accord's RFP No. 16.

Any discussion on the contents of any expert report yet to be served is premature. If Accord still wants to raise an issue on the content of Plaintiffs' expert reports after service, we can discuss then.

Thanks,  
Roman

---

**From:** Alex Menchaca <AMENCHACA@mcandrews-ip.com>  
**Sent:** Monday, October 14, 2024 12:13 PM  
**To:** Cooper, Luke W. <lcooper@sughrue.com>; 'Morgan M. Daughton' <mdaughton@skjlaw.com>; Ben J. Mahon <BMahon@mcandrews-ip.com>; 'Benjamin J. Schladweiler' <schladweilerb@gtlaw.com>; Brad P. Loren <BLoren@mcandrews-ip.com>; Rajendra A. Chiplunkar <RChiplunkar@mcandrews-ip.com>; 'Renee Mosley-Delcollo' <renee.delcollo@gtlaw.com>  
**Cc:** Iyer, Chid S. <ciyer@sughrue.com>; 'Daniel A. Taylor' <DAT@skjlaw.com>; Callahan, John T. <Jcallahan@sughrue.com>; Rachuba, L Roman <lrachuba@sughrue.com>; Dzwonczyk, Michael R. <mdzwonczyk@sughrue.com>; 'Neal C. Belgam' <NCB@skjlaw.com>; Electronic Case Mgmt <E@mcandrews-ip.com>  
**Subject:** RE: Case 1:23-cv-00377-CFC, Ingenus Pharmaceuticals, LLC, et al. v. Accord Healthcare, Inc.

Counsel,

Regarding the attached document, it appears to be a summary of sales information.

Accord also notes that Ingenus disclosed a financial consultant, Stephen Holzen.

As Ingenus is aware, Ingenus has not asserted any allegations of commercial success or other issue that may be addressed by a financial expert or be supported by sales information.

Accord advises that should Ingenus seek to raise in this action any issue related to the attached financial information, such as commercial success, Accord will move to strike any such proposed opinions and evidence. Please advise by return email if Ingenus will seek to raise such issues so that the parties may address the matter now instead of after rebuttal expert reports.

Best regards,  
Alex.



**McAndrews**

**Alejandro Menchaca**

**Attorney at Law**

McAndrews, Held & Malloy, Ltd.

500 W. Madison St., 34th Floor | Chicago, IL 60661

P: 312-775-8103

[amenchaca@mcandrews-ip.com](mailto:amenchaca@mcandrews-ip.com)

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---

**From:** Cooper, Luke W. <[lcooper@sughrue.com](mailto:lcooper@sughrue.com)>

**Sent:** Friday, September 20, 2024 2:16 PM

**To:** 'Morgan M. Daughton' <[mdaughton@skjlaw.com](mailto:mdaughton@skjlaw.com)>; Alex Menchaca <[AMENCHACA@mcandrews-ip.com](mailto:AMENCHACA@mcandrews-ip.com)>; Ben J. Mahon <[BMahon@mcandrews-ip.com](mailto:BMahon@mcandrews-ip.com)>; 'Benjamin J. Schladweiler' <[schladweilerb@gtlaw.com](mailto:schlادweilerb@gtlaw.com)>; Brad P. Loren <[BLoren@mcandrews-ip.com](mailto:BLoren@mcandrews-ip.com)>; Rajendra A. Chiplunkar <[RChiplunkar@mcandrews-ip.com](mailto:RChiplunkar@mcandrews-ip.com)>; 'Renee Mosley-Delcollo' <[renee.delcollo@gtlaw.com](mailto:renee.delcollo@gtlaw.com)>

**Cc:** Iyer, Chid S. <[ciyer@sughrue.com](mailto:ciyer@sughrue.com)>; 'Daniel A. Taylor' <[DAT@skjlaw.com](mailto:DAT@skjlaw.com)>; Callahan, John T. <[jcallahan@sughrue.com](mailto:jcallahan@sughrue.com)>; Rachuba, L Roman <[lrachuba@sughrue.com](mailto:lrachuba@sughrue.com)>; Dzwonczyk, Michael R. <[mdzwonczyk@sughrue.com](mailto:mdzwonczyk@sughrue.com)>; 'Neal C. Belgam' <[NCB@skjlaw.com](mailto:NCB@skjlaw.com)>

**Subject:** Re: Case 1:23-cv-00377-CFC, Ingenus Pharmaceuticals, LLC, et al. v. Accord Healthcare, Inc.

**CAUTION: External Email From:** [lcooper@sughrue.com](mailto:lcooper@sughrue.com)

Counsel,

As the slipsheet sent earlier attests, this document is marked "Highly Confidential – Attorney's Eyes Only." Please replace the native file sent earlier with this one.

Respectfully,

Luke Cooper

Litigation Paralegal

Sughrue Mion, PLLC

[lcooper@sughrue.com](mailto:lcooper@sughrue.com)

202.663.7429

---

**From:** Cooper, Luke W.

**Sent:** Friday, September 20, 2024 2:49 PM

**To:** 'Morgan M. Daughton' <[mdaughton@skjlaw.com](mailto:mdaughton@skjlaw.com)>; 'Alejandro Menchaca' <[amenchaca@mcandrews-ip.com](mailto:amenchaca@mcandrews-ip.com)>; 'Ben J. Mahon' <[bmahon@mcandrews-ip.com](mailto:bmahon@mcandrews-ip.com)>; 'Benjamin J. Schladweiler' <[schladweilerb@gtlaw.com](mailto:schlادweilerb@gtlaw.com)>; 'Bradley P. Loren' <[bloren@mcandrews-ip.com](mailto:bloren@mcandrews-ip.com)>; 'Rajendra A. Chiplunkar' <[rchiplunkar@mcandrews-ip.com](mailto:rchiplunkar@mcandrews-ip.com)>; 'Renee Mosley-Delcollo' <[renee.delcollo@gtlaw.com](mailto:renee.delcollo@gtlaw.com)>

**Cc:** Iyer, Chid S. <[ciyer@sughrue.com](mailto:ciyer@sughrue.com)>; 'Daniel A. Taylor' <[DAT@skjlaw.com](mailto:DAT@skjlaw.com)>; Callahan, John T.

<[jcallahan@sughrue.com](mailto:jcallahan@sughrue.com)>; Rachuba, L Roman <[lrachuba@sughrue.com](mailto:lrachuba@sughrue.com)>; Dzwonczyk, Michael R. <[mdzwonczyk@sughrue.com](mailto:mdzwonczyk@sughrue.com)>; 'Neal C. Belgam' <[NCB@skjlaw.com](mailto:NCB@skjlaw.com)>

**Subject:** Case 1:23-cv-00377-CFC, Ingenus Pharmaceuticals, LLC, et al. v. Accord Healthcare, Inc.

Counsel,

Attached please find a document being produced by Ingenus today.

Respectfully,

Luke Cooper  
Litigation Paralegal  
Sughrue Mion, PLLC  
[lcooper@sughrue.com](mailto:lcooper@sughrue.com)  
202.663.7429

**Luke W. Cooper**



**Sughrue Mion, PLLC**  
2000 Pennsylvania Ave NW Ste 9000  
Washington, DC 20006  
Office: 202-663-7429 | Fax: 202-293-7860  
[lcooper@sughrue.com](mailto:lcooper@sughrue.com) – [www.sughrue.com](http://www.sughrue.com)

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# EXHIBIT F

## Alex Menchaca

---

**From:** Cooper, Luke W. <lcooper@sughrue.com>  
**Sent:** Tuesday, October 29, 2024 4:10 PM  
**To:** 'Morgan M. Daughton'; Alex Menchaca; Ben J. Mahon; 'Benjamin J. Schladweiler'; Brad P. Loren; Rajendra A. Chiplunkar; 'Renee Mosley-Delcollo'  
**Cc:** Iyer, Chid S.; 'Daniel A. Taylor'; Callahan, John T.; Rachuba, L Roman; Dzwonczyk, Michael R.; 'Neal C. Belgam'  
**Subject:** Case 1:23-cv-00377-CFC, Ingenus Pharmaceuticals, LLC, et al. v. Accord Healthcare, Inc. - document production

**CAUTION: External Email From: lcooper@sughrue.com**

Counsel,

In the link below please find the ING006 production. This production is one document, totaling 3 pages and the bates range is ING00133328 - ING00133330. A password will be sent under separate cover.

<https://www.sendthisfile.com/OMGjtbYhbKiSMlyOyaVxfzVe>

Respectfully,

Luke Cooper  
Litigation Paralegal  
Sughrue Mion, PLLC  
[lcooper@sughrue.com](mailto:lcooper@sughrue.com)  
202.663.7429



**Luke W. Cooper**  
Litigation Paralegal  
**Sughrue Mion, PLLC**  
2000 Pennsylvania Ave NW Ste 9000  
Washington, DC 20006  
Office: 202-663-7429 | Fax: 202-293-7860  
[lcooper@sughrue.com](mailto:lcooper@sughrue.com) – [www.sughrue.com](http://www.sughrue.com)

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